

Substitute for form 1449A/PTO				Complete if Known			
				Application Number	Not Yet Assigned		
				Filing Date	September 8, 2003		
				First Named Inventor	Lewis H. Lambert, Jr.		
				Art Unit	Not Yet Assigned		
				Examiner Name	Not Yet Assigned		
Sheet	1	of	4	Attorney Docket Number	29715/33202B		

U.S. PATENT DOCUMENTS							
*Examiner Initials		Document Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
<i>LT.</i>	A01	5,032,574	7/16/91	Wilde et al.	514	12	
	A02	5,089,274	2/18/92	Marra et al.	424	534	
	A03	5,171,739	2/15/92	Scott	514	12	
	A04	5,198,541	3/3/93	Elsbach et al.	435	69.1	
	A05	5,234,912	8/10/93	Marra et al.	514	12	
	A06	5,308,834	5/3/94	Scott et al.	514	12	
	A07	5,334,584	8/2/94	Scott et al.	514	12	
<i>✓</i>	A08	5,348,942	9/20/94	Little, II et al.	514	12	
	A09	5,763,567	6/9/98	Little	530	300	

FOREIGN PATENT DOCUMENTS							
*Examiner Initials		Document Number	Publication Date	Country	Class	Subclas	Translation
<i>LT.</i>	B01	WO 88/06038	08/25/88	WIPO			Yes
	B02	WO 92/03535	3/5/92	WIPO			No
	B03	WO 92/09621	6/11/92	WIPO			
	B04	WO 93/05797	4/4/93	WIPO			
	B05	WO 93/06228	4/1/93	WIPO			
	B06	WO 93/23434	11/25/93	WIPO			
	B07	WO 93/23540	11/25/93	WIPO			
	B08	WO 94/17819	8/18/94	WIPO			
	B09	WO 94/18323	8/18/94	WIPO			
	B10	WO 94/20128	9/15/94	WIPO			
	B11	WO 94/20129	9/15/94	WIPO			
<i>✓</i>	B12	WO 92/14155	8/20/92	WIPO			
	B13	WO 97/42966	11/20/97	WIPO			
	B14	WO 97/44056	11/27/97	WIPO			

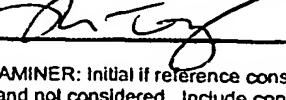
Examiner Signature	<i>LT</i>	Date Considered	06.02.05
--------------------	-----------	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	Not Yet Assigned
				Filing Date	Sept 28, 2003
				First Named Inventor	Lewis H. Lambert, Jr.
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	29715/332028

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)		
<i>Not included</i>	C01	Beaman et al., "Cytokines, Toxoplasma and Intracellular Parasitism", <i>Immun. Rev.</i> 127: 97-117 (1992)
<i>Submitted</i>	C02	Brown et al., "Azithromycin, Rifabutin, and Rifapentine for Treatment and Prophylaxis of <i>Mycobacterium avium</i> Complex in Rats Treated with Cyclosporine", <i>Antimicrob. Agents and Chemother.</i> , 37(3): 398-402 (March 1993)
	C03	Buddeley et al., "Automatic Quantitative Radiometric Assay of Bacterial Metabolism", <i>Clin. Chem.</i> , 22(9): 1459-1464 (1976)
	C04	Chaterjee et al., "Structural Basis of Capacity of Lipoarabinomannan to Induce Secretion of Tumor Necrosis Factor", <i>Infect. and Immun.</i> , 60(3): 1249-1253 (March 1992)
	C05	Collins, "Antituberculous Immunity: New Solutions to an Old Problem", <i>Rev. of Infect. Dis.</i> , 13(5): 940-950 (1991)
	C06	Conforth et al., "Antituberculous Effect of Certain Surface-Active Polyoxyethylene Ethers in Mice", <i>Nature</i> , 168: 150-153 (July 28, 1951)
	C07	Davidson and Le, "Drug Treatment of Tuberculosis - 1992", <i>Drugs</i> , 43(5):651-673 (1992)
	C08	Elsbach et al., "Separation and Purification of a Potent BPI Protein and a Closely Ass. Phospholipase A ₂ from Rabbit Polymorphonuclear Leukocytes", <i>J. Biol. Chem.</i> , 254: 11000-11009 (November 10, 1979)
	C09	Franzblau and Hastings, "Rapid in vitro Metabolic Screen for Antileprosy Compounds", <i>Antimicrobial Agents and Chemotherapy</i> , 31(5): 780-783 (May 1987)
	C10	Friedland, "Cytokines, Phagocytosis, and <i>Mycobacterium tuberculosis</i> ", <i>Lymphokine and Cytokine Research</i> , 12(2): 127-133 (November 2, 1993)
	C11	Gazzano-Santoro et al., "High-Affinity Binding of the BPI Protein and a Recombinant Amino-Terminal Fragment to the Lipid A Region of Lipopolysaccharide", <i>Infect. Immun.</i> , 60: 4754-4761 (November 1992)
	C12	Gray et al., "Cloning of the cDNA of a Human Neutrophil Bactericidal Protein", <i>J. Biol. Chem.</i> , 264: 9505-9509 (June 5, 1989)
	C13	Hastings et al., "Leprosy", <i>Clin. Micro. Reviews</i> , 1: 330-348 (July 1988)
	C14	Hunter et al., "Structure and Antigenicity of the Phosphorylated Lipopolysaccharide Antigens from the Leprosy and Tuberle Bacilli", <i>J. Biol. Chem.</i> , 261: 12345-12351 (September 1986)
	C15	Inderlied, "Antimycobacterial Agents: <i>In Vitro</i> Susceptibility Testing, Spectrums of Activity, Mechanisms of Action and Resistance, and Assays for Activity in Biological Fluids", in <i>Antibiotics in Laboratory Medicine</i> , pp. 134-197, 3rd ed., (V. Lorian ed., The Williams & Wilkins Co., Baltimore) (1991)
	C16	Kelly et al., "Role of Bactericidal/Permeability Increasing Protein (BPI) in the Management of Gram Negative Pneumonia," Presented At the Annual Meeting of the Society of Univ. Surgeons, Feb. 10-14, 1993 (abstract)
<i>✓</i>	C17	Kirchheimer and Storrs, "Attempts to Establish the Armadillo (<i>Dasypus novemcinctus</i> Linn.) as a Model for the Study of Leprosy", <i>Int. J. Lepr.</i> , 39(3): 693-702 (July-September 1971)
	C18	Lalande et al., "Powerful Bactericidal Activity of Sparfloxacin (AT-4140) against <i>Mycobacterium</i>

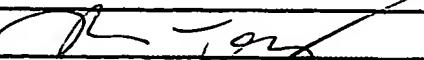
Examiner Signature: 	Date Considered	06/02/05
---	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹Applicant's unique citation designation number (optional). ²See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	Not Yet Assigned
Sheet	3	of	4	Filing Date	September 8, 2003
				First Named Inventor	Lewis H. Lambert, Jr.
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	29715/33202B

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)					
					<i>tuberculosis in Mice", Antimicrob. Agents and Chemo., 37(3): 407-413 (March 1993)</i>
Not included	C19				Little et al., "Functional Domains of Recombinant Bactericidal/Permeability Increasing Protein (rBPI ₂₃)", <i>J. Biol. Chem.</i> , 269(3):1865-1872 (January 21, 1994)
Submitted	C20				Levy et al., "Antibacterial 15-kDa Protein Isoforms (p15s) are Members of a Novel Family of Leukocyte Proteins", <i>J. Biol. Chem.</i> , 268(8):6038-6083 (1993)
	C21				Mittal et al., "Rapid, Radiolabeled-Microculture Method That Uses Macrophages for In Vitro Evaluation of <i>Mycobacterium leprae</i> Viability and Drug Susceptibility", <i>J. Clin. Microbiol.</i> , 17(4): 704-707 (April 1983)
	C22				Ooi et al., "Endotoxin-neutralizing Properties of the 25 kD N-Terminal Fragment and a Newly Isolated 30 kD C-Terminal Fragment of the 55-60 kD Bactericidal/Permeability-Increasing Protein of Human Neutrophils", <i>J. Exp. Med.</i> , 174: 649-655 (September 1991)
	C23				Ooi et al., "Isolation of Two Isoforms of a Novel 15-kDa Protein from Rabbit Polymorphonuclear Leukocytes that Modulate the Antibacterial Actions of Other Leukocyte Proteins", <i>J. Biol. Chem.</i> , 265(26):15956-15962 (September 15, 1990)
	C24				Orme et al., "Inhibition of Growth of <i>Mycobacterium avium</i> in Murine and Human Mononuclear Phagocytes by Migration Inhibitory Factor", <i>Infect. and Immun.</i> 61(1): 338-342 (January 1993)
	C25				Otterlei et al., "Similar Mechanisms of Action of Defined Polysaccharide and Lipopolysaccharides: Characterization of Binding and Tumor Necrosis Factor Alpha Induction", <i>Infect. and Immunity</i> , 61(5): 1917-1925 (May 1993)
	C26				Portaels et al., "Cultivable Mycobacteria Isolated From Organs of Armadillos Uninoculated and Inoculated with <i>Mycobacterium Leprae</i> ", <i>Ann. Inst. Pasteur/Microbiol.</i> , 136: 181-190 (1985)
	C27				Rastogi, "Killing Intracellular Mycobacteria in <i>in vitro</i> Macrophage Systems: What May Be the Role of Known Host Microbicidal Mechanisms?", <i>Res. Microbiol.</i> , 141(2): 217-230 (1990)
	C28				Roberts et al., "Evaluation of the BACTEC Radiometric Method for Recovery of Mycobacteria and Drug Susceptibility Testing of <i>Mycobacterium tuberculosis</i> from Acid-Fast Smear-Positive Specimens", <i>J. of Clin. Microbiol.</i> , 18(3): 689-696 (September 1983)
	C29				Schwab and Mandell, "The Importance of Penetration of Antimicrobial Agents into Cells", <i>Infect. Dis. Clinics of North America</i> , 3(3): 461-467 (September 1989)
	C30				Shah et al., "A Rapid Radiometric Method for Detection of <i>M. Tuberculosis</i> : Optimization of Experimental Conditions", <i>Int. J. Nucl. Med. Biol.</i> , 11(3/4): 283-286 (1984)
	C31				Shepard, "The Experimental Disease that Follows the Injection of Human Leprosy Bacilli into Foot-Pads of Mice", <i>J. Exp. Med.</i> , 112: 445-454 (1960)
	C32				Shepard and Chang, "Effect of Several Anti-Leprosy Drugs on Multiplication of Human Leprosy Bacilli in Foot-Pads of Mice", <i>Proc. Soc. Exp. Biol. Med.</i> , 109: 636-638 (1962)
	C33				Shepard and McRae, "A Method for Counting Acid-fast Bacteria", <i>Int. J. Lepr.</i> , 36: 78-82 (1968)
	C34				Shepard et al., "Experimental Chemotherapy in leprosy," <i>Bull. World Health Organ.</i> , 53: 425-433 (1976)
	C35				Sibley and Krahenbuhl, "Defective Activation of Granuloma Macrophages From

Examiner Signature		Date Considered	06.02.05
--------------------	---	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹Applicant's unique citation designation number (optional). ²See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	September 8, 2003
				First Named Inventor	Lewis H. Lambert, Jr.
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	4	of	4	Attorney Docket Number	
29715/33202B					

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)					
Not included	C36				
Submitted	C37	Sibley and Krahenbuhl, "Induction of Unresponsiveness to Gamma Interferon in Macrophages Infected with <i>Mycobacterium leprae</i> ", <i>Infect. and Immun.</i> , 56(8): 1912-1919 (August 1988)			
	C38	Sibley et al., "Inhibition of Interferon-Gamma-Mediated Activation in Mouse Macrophages Treated With Lipoarabinomannan", <i>Clin. Exp. Immunol.</i> , 80(1): 141-148 (1990)			
	C39	Sibley et al., "Intracellular Fate of <i>Mycobacterium leprae</i> in Normal Activated Mouse Macrophages", <i>Infect. and Immun.</i> , 55(3): 680-685 (March 1987)			
	C40	Sibley et al., "Mycobacterial lipoarabinomannan Inhibits Gamma Interferon-Mediated Act. of Macrophages", <i>Infect. and Immun.</i> , 56(5): 1232-1236 (May 1988)			
	C41	van den Broek, "Activity of Antibiotics against Microorganisms Ingested by Mononuclear Phagocytes", <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , 10(2): 114-118 (February 1991)			
	C42	Weiss and Olsson, "Cellular and Subcellular Localization of the BPI Protein of Neutrophils", <i>Blood</i> , 69: 652-659 (February 1987)			
	C43	Weiss et al., "Human BPI Protein and a Recombinant NH ₂ -Terminal Fragment Cause Killing of Serum-resistant Gram-negative Bacteria in Whole Blood and Inhibit Tumor Necrosis Factor Release Induced by the Bacteria", <i>J. Clin. Invest.</i> , 90: 1122-1130 (September 1992)			
	C44	Kelly et al., "Role of Bactericidal/Permeability-Increasing Protein in the Treatment of Gram-Negative Pneumonia", <i>Surgery</i> , 144(2):140-146 (August 1993)			
✓	C45	Edgington, "How Sweet It Is: Selectin-Mediating Drugs", <i>Bio/Technology</i> , 10:383-386, 388, 389 (1992)			

Examiner Signature		Date Considered	06.02.05
--------------------	--	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹Applicant's unique citation designation number (optional). ²See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.